DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
7200 Lake Ellenor Drive
Orlando, FL 32809

m8661

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

FLA-97-54

April 28, 1997

Jui Teng Lin, President
Photon Data Inc.
7055 University Boulevard
Winter Park, Florida 32792

Dear Mr. Lin:

We are writing to you because on April 1-3, 1997, FDA Investigator Ronald T. Weber, collected information that revealed serious regulatory problems involving products identified as scanning excimer laser systems, which are made and marketed by your firm. This information was collected subsequent and in addition to our previous inspection of your firm in February 1997, for which you received Warning Letter #FLA-97-49.

Under the Federal Food, Drug, and Cosmetic Act (the Act), these products are considered to be medical devices because they are used to diagnose or treat a medical condition or to affect the structure or function of the body. The law requires that manufacturers of medical devices conform with the Current Good Manufacturing Practice (CGMP) for Medical Devices Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820.

The inspection revealed that your devices are adulterated within the meaning of section 501(h) of the Act, in that the methods used in, or the facilities or controls used for the manufacture, packing, storage, or installation are not in conformance with the CGMP. These violations include, but are not limited to the following:

- Failure to document, review, approve, implement and validate changes to components, finished devices, labeling, packaging or process specifications, e.g., changes requested by individual physicians were made without documentation, review, approval or validation prior to the change being implemented.

- Failure to establish and document a formal quality assurance program, e.g., PDI has not produced any written quality assurance procedures.

- Failure to maintain records of component inspection including acceptance and rejection to assure conformance to specifications, e.g., there are no records of component inspection prior to their use in production.

- Failure to conduct planned and periodic internal audits of the quality assurance program pursuant to written procedures.

- Failure to establish and implement adequate recordkeeping procedures, e.g., there are no device history records (DHR) and there are no records of in-processing testing to assure conformance to specifications.

You should know that these violations of the law may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizing your product inventory, obtaining a court injunction against your further marketing of the product, or assessing civil money penalties. Also, other Federal agencies are informed about the warning letters we issue, such as this one, so that they may consider this information when awarding government contracts.

It is necessary for you to take action on this matter now. Please let this office know in writing within fifteen (15) working days from the date you receive this letter what steps you are taking to correct the problem. We also ask that you explain how you plan to prevent this from happening again. If you need more time, let us know why and when you expect to complete your correction. Please direct your response to Timothy J. Couzins, Compliance Officer, Food and Drug Administration, Florida District, 7200 Lake Ellenor Dr., Suite #120, Orlando, Florida 32809.

Finally, you should understand that there are many FDA requirements pertaining to the manufacture and marketing of medical devices. This letter pertains only to the issue of good manufacturing practices for your device and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for manufacturers of medical devices by contacting our Division of Small Manufacturers Assistance at 1-800-638-2041 or through the Internet at http://www.fda.gov.

If you have more specific questions about the GMPs or other FDA requirements affecting your particular device, or about the content of this letter, please feel free to contact Tim Couzins at (407) 648-6823, ext. #264.

Sincerely yours,

Douglas D. Tolen

Douglas D. Tolen
Director, Florida District